

therefore. The Commissioner is hereby authorized to charge any additional fee, or credit any overpayment, to Deposit Account 50-0230.

### INFORMATION DISCLOSURE STATEMENT

As an Information Disclosure Statement, the Examiner's attention is respectfully directed to the accompanying form PTO-1449 along with the copy of the reference therein identified. This reference was cited in the Supplementary European Search Report, a copy of which is also enclosed. Entry of this Information Disclosure Statement is respectfully solicited, and it is respectfully requested that the Examiner initial and return a copy of the accompanying PTO-1449.

### REMARKS

Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

The March 18, 2002 Office Action called for restriction from among the following:

- Group I:        Claims 43-95, drawn to a method, classified in class 435, subclass 325; and
- Group II:       Claims 1-42, drawn to an apparatus, classified in class 435, subclass 289.1.

Group I is elected, with traverse.

The MPEP lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

The Office Action states that the “inventions are distinct ... because ... [the] [i]nventions of Group I and II are related as process and apparatus for its practice.” Office Action at 2.“

The Office Action also states that “the apparatus can be used for bioremediation of hazardous wastes.” *Id.* The Office Action maintains that this satisfies the requirement that the apparatus as claimed can be used to practice another and materially different process, thereby alleging that the inventions of Group I and II are distinct. Applicants respectfully disagree.

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The apparatus claims of Group II include two independent claims, upon which the remaining claims depend. These independent claims are set forth below:

1. An apparatus for growing cells comprising  
at least one bioreactor for cell culture  
at least one vessel for culture medium,  
means for circulating culture medium and/or cell culture, whereby the  
bioreactor and vessel are in fluid communication, and  
at least one means for delivery of oxygen.
8. An apparatus for growing cells comprising  
a bioreactor for cell culture  
a vessel for culture medium,  
means for circulating culture medium  
dialysis means in fluid communication with the bioreactor and the vessel,  
whereby, there is  
a first, cell culture, loop between the bioreactor and the dialysis  
means, and  
a second, media replenishment, loop between the vessel and the  
bioreactor,  
and in operation dialysis between the culture medium and cell culture.

It is respectfully pointed out that in order for the Office Action's assertions of an alternate use for the claimed apparatus to be valid, the apparatus as set forth above in claims 1 and 8 must be able to be used for bioremediation of hazardous wastes without deviating from the limitations present in claims 1 and 8.

The present invention provides for a vessel for culture medium, and a vessel for cell culture. These vessels are in fluid communication with each other, through the circulation of either the cell culture or the culture medium, or, as in claim 8, through a dialysis means. The claims do not provide for the delivery of any additional components into the apparatus, save for oxygen. In order for such an apparatus to be used for bioremediation of hazardous wastes, the hazardous wastes would need to be in fluid communication with the components of the apparatus, which implies that the wastes would have to be introduced into the cell culture itself or into the culture medium. It is respectfully submitted that neither alternative would allow for bioremediation as is suggested by the Office Action. The limitations on the contents of the vessels, as described in both claims 1 and 8, would prohibit the use of the apparatus for bioremediation of hazardous wastes.

Consequently, it is respectfully submitted that the suggestion of remediation of hazardous wastes as an alternate use for the apparatus of the Group II claims is clearly in error, and should not be considered to meet the requirements set forth in MPEP §806.05(e) for identifying distinct inventions. On this basis alone, the Restriction Requirement should be withdrawn.

Additionally, Applicants respectfully urge that the Restriction Requirement does not establish that searching all the claims would constitute an undue burden to the Patent Office. In fact, nowhere in the Office Action is it even mentioned that an undue burden would be placed on the Examiner by searching all of the claims.

In fact, it does not seem possible that searching the claims of both Group I and II could pose a burden to the Examiner, as the present Examiner both provided the search for, and wrote, the International Search Report in corresponding international application PCT/US00/01568, which contained 95 claims identical to those currently pending the instant application. To this end, our February 26, 2002 Communication provided the Examiner with the following:

- (a) The Amendment pursuant to PCT Rule 66.1(b) and Article 34, made in corresponding PCT application PCT/US00/01568;
- (b) The June 6, 2001 Notification of Transmittal of International Search Report (IPER) and IPER and the documents it cites (Guinn et al., USP 4,889,812, Portner, R. Dialysis cultures. Appl. Microbiol., Oct. 1998, Vol. 50, pages 403-414, Kamen A., On-line Monitoring of Respiration in Recombinant —Baculovirus infected and Uninfected Insect Cell Bioreactor Cultures. Biotechnology and Bioengineering, Oct. 1995, Vol. 50, pp. 36-48, and Spaulding USP 5,637,477);
- (c) The April 5, 2001 Written Opinion in the corresponding PCT application and the documents it cites;
- (d) The August 6, 2001 Notification of Transmittal of IPER and IPER; and
- (e) An October 16, 2001 letter from Canadian Associate regarding corresponding Canadian application, and proposed claim set therefor, based on claims deemed to meet PCT Article 33(2)-(4) An of corresponding PCT application.

It is respectfully submitted that these documents prevent the Examiner from being subjected to any alleged unnecessary burden posed by the examination of the claims of both Group I and II. Essentially, the search and examination of the claims has already been performed, and was carried out and reported by the current Examiner during examination of the corresponding PCT application.

As previously stated, the Examiners are to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions." MPEP § 803. As no serious burden would be caused by examination of the claims of both Group I and II, the Restriction Requirement is improper, and must be withdrawn.

In summary, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the suggested alternate utility for the apparatus is improper, and since the requisite showing of serious burden has not been made. Indeed, the search and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner, especially as the Examiner has previously searched and examined the entire application while preparing the IPER in the corresponding international application. All of the preceding, therefore, mitigate against restriction.

#### CONCLUSION

In view of the remarks herein, reconsideration and withdrawal of the restriction requirement are requested. Early and favorable consideration of the application on the merits, and Allowance of the application are earnestly solicited.

Respectfully submitted,

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